DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Food and Drug Administration

Display Date 12-13-01
Publication Date 12-14-01
Certifier N. Sunkara

[Docket No. 01N–0393]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Product Labeling; Medication Guide Requirements (OMB Control No. 0910–0393)—Extension

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included are information such as the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA. The estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.

21 CFR 314.70(b)(3)(ii) and 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under § 208.26 (21 CFR 208.26).

Section 208.26(a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
208.20	8	1	8	242	1,936

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
314.70(b)(3)(ii) and 601.12(f)	3	1	3	24	72
208.24(e)	55,000	8.3	460,000	.0014	644
208.26(a)	1	1	1	4	4
Total					2,656

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of September 25, 2001 (66 FR 49024), the agency requested comments on the proposed collections of information. FDA received one comment on the September 25, 2001, notice. The comment stated that clarification is needed as to whether Medication Guides would be needed for medical devices that have a prescription drug either as a coating or incorporated into the material of the device, or as a component in a kit. The comment said that some of these types of products might be considered combination products.

FDA requested comments on the information collection burden estimates described in the notice. Because the comment does not pertain to the burden estimates, FDA has forwarded the

comment to Docket Number 93N–0371, "Prescription Drug Product Labeling; Medication Guide Requirements." FDA appreciates the comment and will consider it as part of its Medication Guide program.

Dated: 12-7-01

December 7, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

BILLING CODE 4160–01–S

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